

REMARKS

I. Status of the Claims

Claims 98-112 are pending and have been made the subject of a restriction requirement.

II. Response to the Restriction Requirement

The Office has required restriction between Groups I-X, characterized by the examiner as follows:

Group I claim(s) 98-117 (in part), drawn to a compound of formula (A) wherein: R₁ is phenyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 548.

Group II claim(s) 98-117 (in part), drawn to a compound of formula (A) wherein: R₁ is furanyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 548.

Group III claim(s) 98-117 (in part), drawn to a compound of formula (A) wherein: R₁ is thienyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 548.

Group IV claim(s) 98-117 (in part), drawn to a compound of formula (A) wherein: R₁ is pyridyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 546.

Group V claim(s) 98-117 (in part), drawn to a compound of formula (A) wherein: R₁ is pyrimidyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 544.

Group VI claim(s) 118-122 (in part), drawn to a method of use for a compound of formula (A) wherein: R₁ is phenyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 514.

Group VII claim(s) 118-122 (in part), are drawn to a method of use for a compound of formula (A) wherein: R₁ is furanyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 514.

Group VIII claim(s) 118-122 (in part), drawn to a method of use for a compound of formula (A) wherein: R₁ is thienyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl,

C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 514.

Group IX claim(s) 118-122 (in part), drawn to a method of use for a compound of formula (A) wherein: R₁ is pyridyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 514.

Group X claim(s) 118-122 (in part), drawn to a method of use for a compound of formula (A) wherein: R₁ is pyrimidyl; R₂ is C₁₋₆ alkyl, C₂₋₆ alkenyl, C₂₋₆ alkynyl or C₃₋₇ cycloalkyl; R₃ is as defined in claim 98 excluding heteroaryl; R_{3a} is as defined in claim 98; R₄, R_{4a}, R₅, R_{5a}, are each as defined in claim 98 excluding 5 or 6 membered-heteroaryl; R₆ and R₇ are each independently selected from the group consisting of H, C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group; wherein each said C₁₋₆ alkyl, C₂₋₆ alkenyl, C₃₋₇ cycloalkyl, phenyl and benzyl group is optionally substituted with 1 to 5 substituents selected independently from the group as defined in claim 98, classified in various subclasses in class 514.

The Office Action states that the listing provided is "exemplary" and "not exhaustive". The Office offers the applicants, as an alternative to electing one of the groups, the option of electing a specific compound.

The applicants **elect Group I, but respectfully traverse the restriction requirement.** The applicants respectfully submit that the restriction requirement made is improper, at least because: (A) the Office has not demonstrated that the claims lack unity of invention; (B) the Groups from which election is being required are arbitrary and improper; (C) no undue burden of searching the entire scope of the invention has been established; (D) the restriction requirement is incomplete; and (E) the restriction requirement is unclear.

(A) Unity of Invention

The Office states that unity is lacking because the inventions of Groups I-X are allegedly not so linked as to form a single general inventive concept under PCT Rule 13. It is unclear how this conclusion is drawn because the Office provides no analysis of whether these groups share the same or corresponding special technical features. Further, the Office acknowledges that the Groups of inventions listed do not encompass the entirety of the claimed subject matter. Accordingly it is unclear how the Office conclude that all the unidentified subject matter outside the enumerated Groups lacks a shared special technical feature with any of the enumerated Groups. As discussed in greater detail herein, the compounds of formula (A) as defined in claim 98 do in fact share substantial common structural features which are sufficient to establish unity of invention of claims 98-122 under P.C.T. Rule 13.

(1) The Applicable Legal Standard for Unity of Invention

"Unity of invention (not restriction) practice is applicable in ... national stage applications submitted under 35 U.S.C. 371." MPEP 1893.03(d). Unity of invention must be determined under the provisions of the P.C.T. in a national stage application filed under 35 U.S.C. § 371. *Caterpillar Tractor Co. v. Com'r Pat. & Trademarks*, 650 F.Supp. 218 (E.D. Va. 1986). Therefore the legal standards applicable to making a restriction requirement in an application filed under 35 U.S.C. § 371 are those set forth for determining unity of invention under the P.C.T. as given in the P.C.T. itself and the P.C.T. rules (specifically Rule 13).

The standard for unity of invention under the P.C.T. as set forth in P.C.T. Rule 13, states:

"the requirement of unity of invention ... shall be fulfilled ... when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art"

P.C.T. Rule 13.2. Unity of invention is satisfied when there is a special technical feature linking the claims. The presence of a special technical feature linking the claims thus defines the unity of invention standard.

Authoritative guidelines for determining whether there is unity of invention in specific situations are provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions") and also in Chapter 10 of the P.C.T. International Search and Preliminary Examination Guidelines (the "Preliminary Examination Guidelines"). Particular standards set forth in these guidelines that are relevant to unity of invention in the present application are discussed in greater detail below.

First, where there is unity of invention within and among independent claims, there is also unity of invention among dependent claims. The Administrative Instructions explain that unity of invention should be considered first in relation to the independent claims. Then, "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

Second, there is unity of invention as between a claims to a product, and claims to methods of making and using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 should be construed as permitting "in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

Third, the Administrative Instructions establish that when a series of chemical compounds is defined in a claim using so-called "Markush practice" enumerating alternative elements, "[t]he fact that the alternatives of a Markush grouping can be differently classified shall not, taken alone, be considered to be justification for a finding of a lack of unity of invention." Administrative Instructions under the P.C.T. Annex B, para. (f)(iv). Unity of invention is satisfied when a significant structural element is shared by all of the alternatives. The significant structural element may be a single component or a combination of individual structural elements linked together. Administrative Instructions under the P.C.T. Annex B, para. (f).

(2) The Common Features of the Compounds of Formula (A) Constitute Special Technical Features Linking the Claims

Although it is not explicitly stated, the Office appears to consider that the mere existence of variable substituents in the definition of Formula (A) somehow establishes lack of unity of invention of the claims. See the Office Action at p. 3 beginning on line 12; p. 8 lines 4-5. The applicants respectfully point out that claims can have unity of invention even though they might encompass a diversity of compounds and might vary in classification, so these factors are irrelevant to the issue of unity of invention. It is the presence of a special technical feature which determines whether there is unity of invention.

The Office has not established that the common features of the compounds according to Formula (A) do not constitute a special technical feature linking the claims. Indeed, the Office has not established that the invention Groups identified in the Office Action lack unity of invention over each other.

The compounds according to Formula (A) (Figure 1) in fact have numerous common features.

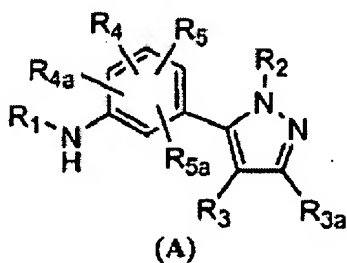


Figure 1. Common Structural Features of the Compounds According to Formula (A).

Theses common features include, for example:

- a phenyl ring substituted by an amino group (R₁NH) and a pyrazole ring;
- the R₁NH amino group and pyrazole ring substituting the phenyl group are in a 1,3-relationship relative to each other

- the amino group is substituted by a second aromatic ring (R_1) optionally substituted with a limited range of substituents as described in the definition of R_1 ;
- the pyrazole ring is attached to the phenyl ring at the 5-position; and
- the pyrazole ring has an aliphatic hydrocarbon substituent (R_2) at the 1-position.

These common features may be represented by the following substantial common substructure of all the compounds according to formula (A) (where * represents points of attachment of optional substituents represented by substituents R_3 , R_{3a} , R_4 , R_{4a} , R_5 , and R_{5a}):

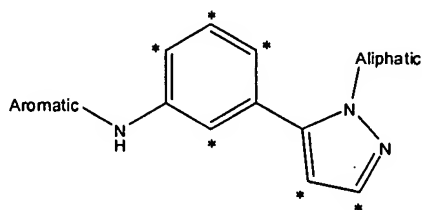


Figure 2. Common Structural Features of the Compounds According to Formula (A).

The different definitions of R_1 in Groups I-V do not establish lack of unity of invention. The principal difference between compounds of Groups I-V is in the definition of R_1 as phenyl, furanyl, thienyl, pyridyl, or pyrimidinyl. All of these groups (and all of the options for R_1 in Formula A as defined in claim 98) belong to a recognized class, namely aromatic rings. The art recognizes aromatic rings as a single class which includes both carbocyclic and heterocyclic rings, and encompasses conjugated unsaturated ring systems with $4n+2$ pi electrons. As the WIPO guidelines point out, the possibility that the alternatives of a Markush group *could* be differently classified is not sufficient justification for a finding of lack of unity of invention. The fact that options available for R_1 include phenyl, furanyl, thienyl, pyridyl, or pyrimidinyl etc. therefore does not defeat unity of invention. All of these options for R_1 , although capable of being differently classified, nevertheless belong to the art recognized class of aromatic rings. The Office has not established that compounds according to Formula (A) having R_1 as an aromatic ring (whether carbocyclic or heterocyclic) do not constitute an advance over the prior art so as to justify the finding of lack of unity of invention. The fact that the options for R_1 are all aromatic rings is sufficient to link Groups I-V (as well as compounds according to formula (A) which do not fall within the definitions provided for these Groups).

The arbitrary exclusion of heteroaryl groups from the definitions of R₃, R₄, R_{4a}, R₅, and R_{5a} in the Office's definitions of each of Groups I-V (e.g. "R₃ is defined is as defined in claim 98 *excluding heteroaryl*") does not appear to be related to whether the inclusion of heteroaryl groups in these definitions establishes lack of unity of invention. The applicants respectfully submit that the common sub-structural features of the compounds according to Formula A are a special technical feature without regard to whether the variable substituents R₃, R₄, R_{4a}, R₅, and R_{5a} might encompass heteroaryl groups.

Although the applicants recognize that the nature of the patent classification system makes it *convenient* for the Office to separate the searches of Groups of compounds having different heterocyclic systems (as reflected in the different heterocyclic rings defined for R₁ in Groups I to V) (since different heterocyclic systems are differently classified), a requirement for restriction in an application in a National Phase application filed under 35 U.S.C. § 371 must be based upon a proper finding of lack of unity of invention under the P.C.T. rather than an arbitrary division of applicants' claims according to what might be convenient for the Office.

The court in *In re Harnisch*, 631 F.2d 716 (CCPA 1980) applied the standard of unity of invention in relation to the propriety of a restriction requirement in a domestic application. Unity of invention was held to exist where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility. MPEP 803.02. The claims to the compounds claim 98 clearly meet the unity of invention standard as defined in *Harnisch*, at least because:

(1) the compounds share the *common utility* of modulating the activity of the 5HT_{2A} receptor;

(2) the compounds *share a substantial structural feature* as defined above;

(3) the structure of the compounds as defined in formula I will be understood to be *essential to the utility* of the compounds because it is well known that biological activity of pharmaceutical compounds is a result of the molecular interaction between the compounds and the biological macromolecules that are the effectors of the biological response, and hence dependent on the molecular structure of the compounds.

Applicants further point out that the substituents R₁-R₆, are variable substituents attached to the core which represents a common structural feature in much the same way that the claim at issue in *Harnisch* defined variable substituents attached to a common core and therefore the fact that these substituents may be variable does not detract from the fact that the claims to the compounds according to formula (A) comply with the unity of invention requirement.

Although the Office cites WO2004/046118 ("WO'118") to support its contention that the claims lack unity of invention, the reference cited does not support the Office's position. Although a prior art reference describing a particular feature of the claims may establish that such a feature does not qualify as a special technical feature because it does not define a contribution over the prior art, no such case is made out by the Office's citation to WO'118. The Office cites WO'118 without any explanation of how the reference supposedly defeats unity of invention. The reference does not appear to describe compounds having all the features of the compounds according to formula (A).

No case has been made that the features of the compounds according to formula (A) do not constitute a special technical feature linking the claims. Accordingly, the claims have not been shown to lack unity of invention, and the restriction requirement is therefore improper.

(3) The Use Claims 118-122 Share Unity of Invention with Compound Claims 98-117 Based upon the Common Features of the Compounds According to Formula A as a Special Technical Feature and the Dependency of these Claims

The restriction requirement is also inconsistent with the standards for unity of invention under the P.C.T. and manifestly improper insofar as restriction is being required among claims to compounds and compositions (in Groups I-V) and methods of using these compounds (in Groups VI-X). The impropriety of the restriction requirement is apparent at least because the novel compounds constitute a special technical feature linking the claims to the compounds with the claims to methods for their use.

The impropriety of the division of the method of use claims 118-122 from the compound claims of claims 98-117 is apparent from at least two of the guidelines for the determination of

unity of invention provided in the Annex B to the Administrative Instructions under the P.C.T. (the "Administrative Instructions"):

(1) Unity of invention is apparent from the dependency of claims 118-122 from claim 98. The Administrative Instructions explain that "[i]f the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims" Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

(2) Unity of invention is also apparent because claims 98-117 and claims 118-122 are related as claims to a product, and claims to methods using the product. The Administrative Instructions explain that the standard for unity of invention under Rule 13.2 permits "in addition to an independent claim for a given product ... an independent claim for a use of the said product." Administrative Instructions under the P.C.T. Annex B, para. (c)(i).

(B) Even If Lack of Unity of Invention Were Established the Groups From Which Election is Being Required are Arbitrary and Improper

(1) The Restriction Requirement Abridges The Applicants Right To Claim The Generic Subject Matter Which The Applicants Regard As Their Invention

According to 35 U.S.C. § 112, the claims of an application must describe "the subject matter *which the applicant regards* as his invention." 35 U.S.C. § 112. The restriction requirement, if maintained, would violate the applicants' right to claim what they regard as their invention by requiring the claims to be rewritten in a manner where generic terms the applicants have used in describing their invention to have to be replaced by different terms having a different meaning. For example, the Office would have the applicants substitute the generic definition of R₁ as "aryl or heteroaryl each optionally substituted ..." by narrower definitions as *particular* aryl or heteroaryl rings, i.e. as phenyl, furanyl, thienyl, pyridyl, pyrimidinyl, etc.

The right of the Office to insist upon restriction when an application claims more than one invention does not give the right for the Office rewrite the applicants' claims to an invention

that has properly been described using *bona fide* generic terms. The fact that the claims might encompass more than one invention in the sense of dominating them is an insufficient reason for maintaining a restriction requirement where a generic claim encompasses more than one of the inventions. See *In re Weber*, 580 F.2d 455, 460 (C.C.P.A. 1978) (Rich J. concurring) (noting that "the obvious fact that almost any reasonably broad claim 'embraces' or 'covers' a multiplicity of inventions, in the sense of 'dominating them' ... is not a sufficient excuse for refusing to examine a claim on its merits for compliance with 35 U.S.C. §§ 101, 102, 103, and 112.") That the compounds of Groups I-V are dominated by claim 98 therefore does not detract from the fact that claim 98 properly claims applicants' invention in generic terms.

(2) The Arbitrary Definitions of the Groups Would Deprive the Applicants of Their Right To Claim The Entirety of Their Invention

A proper restriction requirement should encompass and account for all elements of the original claims, without any voids or ambiguities, so that applicants' entire claimed invention may be examined eventually. An applicant has a right to have each claim examined on the merits in its entirety. *In re Weber*, 580 F.2d 455 (CCPA 1978). The totality of any fragmentary claims must necessarily be the equivalent of the original claim. *Id.* at 458. The applicant has a right to claim his invention as he chooses, and this statutory right takes priority over perceived administrative needs. *Id.* at 459.

By splitting the compound claims in the manner proposed in the restriction requirement, the Office is creating artificial genera that are different from those claimed in the application. The invention claimed in claim 98 (for example) is the compound wherein R₁ is "aryl or heteroaryl", and not a compound wherein R₁ is selected from phenyl, furanyl, thienyl, pyridyl, pyrimidinyl, etc. The invention claimed in claim 98 is also not a compound wherein heteroaryl groups are excluded from the definitions of R₃, R₄, R_{4a}, R₅, and R_{5a}. If the applicants are to pursue subject matter of their invention according to the division proposed by the Examiner, they would be forced to divide and reformulate the subject matter into multiple claims that comply with the restriction and written description requirements by canceling various subject matter. As a result, the scope of the resulting fragments would not equal the originally claimed scope as required, being marred with voids and ambiguities of inaccessible subject matter. Accordingly,

the applicants would have no choice but to forego rights to subject matter to which they are entitled. Forced forfeiture of rights resulting from the contrived and artificial delineation of the compound claims as specified in the Office action merely due to administrative conveniences is clearly beyond the bounds of statutory authority as discussed in *In re Weber*, supra.

(3) Even If Lack of Unity of Invention Were Established, The Arbitrary Definitions of the Groups Would Limit Applicants' Invention More Than Could Conceivably Be Required To Restore Unity of Invention

Even if unity of invention is found to be lacking as to one or more claims, the Office is not thereby given "carte blanche" under the P.C.T. to divide applicants' claims as he sees fit because applicants have the "right to include in a single application ... those inventions which are so linked as to form a single general inventive concept", MPEP 1893.03(d). Therefore even if there is lack of unity of invention as to some of the claims, restriction is permissible only to the extent necessary to restore unity of invention. The applicants are entitled to retain in the application all of the subject matter sharing unity of invention with the applicants' elected Group.

Focusing on the applicants' elected Group, even if the Office had been successful in showing lack of unity of invention, the Office does not explain why R₁ should be limited only to phenyl and not other carbocyclic aromatic groups within the definition of "aryl" as claimed in claim 98. The Office also does not explain why having R₃, R₄, R_{4a}, R₅, and R_{5a} as heteroaryl groups would be inconsistent with unity of invention, and therefore the applicants should also be permitted to retain this subject matter. There is also no basis for the Office to require restriction between the compound and method of use claims from the compound claims, since claims to a product and method of its use share unity of invention under proper P.C.T. practice described above.

(C) Undue Burden

MPEP 803 explains that if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though restriction might otherwise be proper. *See* MPEP 803.

The Office's contention that a search of all the products and methods is unduly burdensome is not compelling. In view of the substantial structural similarities shared by all compounds according to formula (A), it would clearly not constitute an undue burden for the Office to search all of the claims together. For example, the substantial sub-structure identified above could serve as the basis for a computational search in the Chemical Abstracts database, and thus could readily be searched together by the Office.

(D) Incompleteness of the Restriction Requirement

MPEP 815 explains that "[w]hen making a restriction requirement every effort should be made to have the requirement complete." It is apparent from the Office Action that the restriction requirement is not complete because the Office Action states that not all of the inventions have been listed.

(E) Lack of Clarity of the Restriction Requirement

When making a restriction requirement, the Office must "provide a *clear and detailed record* of the restriction requirement to provide a clear demarcation between restricted inventions so that it can be determined whether inventions claimed in a continuing application are consonant with the restriction requirement and therefore subject to the prohibition against double patenting rejections under 35 U.S.C. 121." MPEP 814 (citing *Geneva Pharms. Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1381 (Fed. Cir. 2003)). The restriction requirement made in the present application does not meet this criterion by virtue of its incompleteness. It is not clear what inventions are not listed.

(F) Conclusion

Based on the foregoing, it is respectfully submitted that the requirement for unity of invention is satisfied because the common features of the compounds according to formula (A) as defined in claim 98 constitute a special technical feature linking the claims. Since a restriction requirement made in an National Phase Application filed under 35 U.S.C. § 371 is improper when the requirements of unity of invention is satisfied, it is respectfully submitted that the

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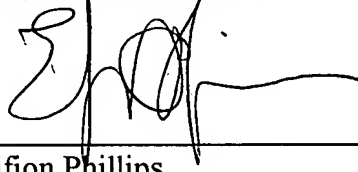
restriction requirement made in the Office Action mailed August 30, 2007 is improper and should be withdrawn. The applicants respectfully request that the restriction requirement made be withdrawn and that the Office proceed to the examination of the full scope of the applicants' claims.

Please apply any charges or credits to Deposit Account No. 06-1050.

Date: _____

2/28/2008

Respectfully submitted,



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